

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

EDWARDS LIFESCIENCES, LLC, et al.,

Plaintiff,

v.

COOK INCORPORATED, et al.,

Defendants.

No. C 03-03817 JSW

**NOTICE OF QUESTIONS FOR
HEARING**

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD, PLEASE TAKE
NOTICE OF THE FOLLOWING QUESTIONS FOR THE CLAIM CONSTRUCTION
HEARING SCHEDULED ON **March 14, 2007** at 2:00 p.m.:

1. Many of the disputed terms are lengthy phrases, which appear to contain terms that are not seriously in dispute or contain terms that the Court will construe separately. The Court requests the parties focus on those portions of these phrases that are truly disputed. For example:
 - a. In disputed term eight (8) are the true disputes are over the meaning of the phrases “being dockable to” and “while inside of a vessel?”
 - b. In disputed term six (6), because the parties separately seek construction of the term “graft,” is the true dispute over the meaning of the phrase “which is adapted to be anchored within one of the flow lumens?”
 - c. In disputed term ten (10), are the true disputes over the meaning of the phrases “to define a single flow lumen” and “to define a continuous flow passage?”

(See, e.g., Amended Joint Claim Construction and Prehearing Statement at 134 n.4.)

d. Why should the Court consider each of these lengthy terms, rather than the smaller phrases that are truly in dispute?

2. Should the Court impart any significance to the fact that, with respect to the term “prosthesis,” as used in claim 1 of the ‘458 Patent, only subsection (ii) of the claim requires “anchoring.” (See also claim language in ‘073 Patent, claiming “graft comprising ... first graft body ... and a supplemental graft body” where it is the supplemental graft body, rather than primary graft body, that contains the “being dockable” limitation.) Indeed, why does this not support Plaintiffs’ argument that the term “prosthesis” should not be construed to require an “intraluminal” limitation?

3. a. Do Defendants agree with the general proposition that, unmodified, the term prosthesis generically refers to an artificial device that would substitute or repair or replace a part of the body? At the very least, do all parties agree that the term “prosthesis” refers to something artificial?

b. The Court does not understand Gore’s proposed requirement that the “prosthesis” be a “multi-component” device. Is Gore arguing that the prosthesis must contain both a “bifurcated base structure” and “a graft” and that each of these structures on their own cannot comprise a “prosthesis?” If the Court is correct in its understanding, how do Plaintiffs reconcile the fact that the claim language reads “a prosthesis comprising (1) a bifurcated base structure ... and (2) a graft...” (See ‘458 Patent at 6:11-17) (emphasis added). That is, why does the word “and” not necessarily support Gore’s argument that the prosthesis must be comprised of at least these two components?

c. How do Cook and Gore support their construction of the term “prosthesis,” in light of the fact that Claim 10 of the ‘458 Patent requires that the prosthesis comprises, *inter alia*, a second graft “adapted to be intravascularly inserted into a

lumen.” Does that not support Plaintiffs’ position that the term “prosthesis” could have a broader meaning than Cook and Gore urge upon the Court?

- d. Is there truly a dispute over whether the “prosthesis” “repairs or replaces” rather than substitutes for a “missing or defective part of the body?” Can the parties come to some agreement on that issue?
- e. Would Plaintiffs agree that only claims 1 and 10 of the ‘458 Patent could contemplate what the Court, for the sake of convenience, shall refer to as a “sewn-in” prosthesis?
- f. Do the parties intend that the term “prosthesis” as used in Claim 10 of the ‘458 Patent should be construed in the same fashion as the term is used in Claim 1? If so, is there any significance with respect to the fact that claim 10 describes a “prosthesis” comprising, *inter alia*, a first graft rather than a bifurcated base structure?
4. a. With respect to the term “graft,” the specification contains many references to an intraluminal graft “according to the present invention” or to the intraluminal graft as “the present invention.” Similarly, it appears to the Court that the unmodified term “graft” often is used as shorthand for “intraluminal graft.” (*See, e.g.*, ‘458 Patent, col. 1, ll. 20-34 (“Such intraluminal grafts are inserted through the femoral artery into the aorta in catheter. Upon release of the graft from the catheter... .”); col. 3, ll. 64-67 (“When the intraluminal graft is inserted into a vessel those wire ends which engage the inside surface of the vessel wall will assist the graft from inadvertent movement along the vessel.”). Although generally a court should not limit the scope of the patent to a preferred embodiment, why does the use of this language not suggest that Plaintiffs disavowed non-intraluminal grafts?
- b. The ‘458 Patent also uses the term “graft,” (‘458 Patent, col. 6, ll. 17), and that term also is used in other portions of claim 1 of the ‘073 Patent (‘073 Patent, col. 6, ll. 45-50). Do the parties maintain that the term “graft,” as it is used in the

preambles to the '073 and '736 Patents, carries the same meaning in the body of the claims? If not, why would that not support a construction of the term graft that is not limited to an intraluminal device?

5. a. Are the references in the specification to the fact that the “graft body is preferably formed of a thin biocompatible material such as Dacron or PTFE,” and “[t]he intraluminal graft 10 comprises a crimped tube 16 of woven dacron” the only intrinsic evidence supporting Plaintiffs’ argument that the terms “graft” and “graft body” should be construed to include the requirement that it be “formed of polymer (plastic)?”
- b. The specification references cited by Defendants appear to clearly distinguish the “graft body” and the “material” from which it is made, from the wires. (*See, e.g.,* '458 Patent, col. 3 ll. 8-25 (“If the graft body is of a woven material the wires may be interwoven with the graft body); *see also id.* col. 1 ll. 20-22 (“It is known to form such an intraluminal graft of a sleeve in which is disposed a plurality of self-expanding wire stents.”) Why do these references not support Plaintiffs’ position that the graft body need not include wires?
6. The terms “bifurcated base structure,” “bifurcated base graft structure,” and “pair of connector legs,” each are followed by the phrases “which defines” or “which define.” Are these terms intended to be definitional?
7. With respect to Defendants’ arguments that the disputed claim terms must be construed to limit the claimed devices to balloon-expandable devices, and recognizing that the following is extrinsic evidence, how do Plaintiffs’ explain Dr. Gordon’s deposition testimony that “Geoff’s graft is by definition a balloon-expandable graft?” (Cook Ex. 13 at 70:9-10.)
8. In the *Phillips* case, the Federal Circuit noted that one problem with relying on extrinsic expert testimony during the claim construction process, is that often “expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Phillips*, 415 F.3d at 1318.

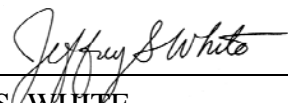
1 Defendants urge the Court not to rely on the declarations submitted by Plaintiffs
2 regarding the interference proceedings.

- 3 a. Do Defendants have any authority that such declarations would raise the same
4 concerns as expert reports or testimony generated in connection with
5 infringement proceedings?
- 6 b. If one reads Dr. White's February 18, 2000 declaration in support of the
7 interference proceeding carefully, it seems to contain a duplicate reference to the
8 October 6, 1993 surgery. (2/18/00 Decl. ¶ 11, ¶ 13.) In paragraph 11, Dr. White
9 states that "On October 6, 1993, I performed an endovascular repair of an [AAA]
10 utilizing an endovascular graft having the features of a wireformed supported
11 prosthesis which could be overlapped within another prosthesis." In paragraph
12 13, he states "On October 6, 1993, I assisted with an endovascular repair of an
13 [AAA] utilizing an endovascular graft having the features of a wireform
14 supported prosthesis which could be overlapped within another *similar*
15 prosthesis." (*Compare* 2/18/00 White Decl. ¶ 11 *with* ¶ 13 (emphasis added).)
16 The latter paragraph seems to be consistent with paragraph 9, in which Dr. White
17 states that Dr. Yu prepared grafts to be used in the bench testing which "had the
18 features of a wireform supported prosthesis which could be overlapped within
19 another *similar* prosthesis." (*Id.* ¶ 9 (emphasis added).) The use of the term
20 "similar" conveys to the Court that the second prosthesis referenced in
21 paragraphs 9 and 13 also was "wireform supported." What, if anything, should
22 the Court conclude from these paragraphs with respect to the Defendants'
23 arguments that the inventions disclosed in the patents-in-suit cannot be construed
24 to include traditional vascular grafts?
- 25 9. Is the Court correct in understanding that the term "intraluminal graft" was deleted from
26 the claims initially submitted the application for the '458 Patent to overcome a double-
27 patenting rejection based upon the '904 Patent?
28

10. With respect to disputed term six (6) (“Graft [structure] which is adapted to be anchored within one of the flow lumens”) Edwards states that “the parties seem to be in agreement that the structure that allows the anchoring to occur is the wires.” (Opening Brief at 18:6-7.) Is Edwards conceding that wires are the only “structure” that could perform this function?
11. With respect to the disputed “substantially all flow” term and Defendants’ argument that the ‘736 and ‘073 Patents do not encompass a bifurcated device, how do Defendants explain the references in the specification to trouser grafts and the fact that the preambles use the open-ended term “comprising?” If the Court were to reject Defendants’ arguments regarding a “tubular” limitation for this term, could the parties agree on a construction? The Court notes that, apart from the bifurcation dispute, the parties’ proposed constructions are similar.
12. When Plaintiffs refer to a scallop “underneath the wire structures” are they referring to a scallop that would be directly below the arch of the wire (17) as depicted in figures 6 and 7 of the patents-in-suit?

IT IS SO ORDERED.

Dated: March 12, 2007



JEFFREY S. WHITE
UNITED STATES DISTRICT JUDGE